FEP Medical Policy Manual

FEP 7.01.106 Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Effective Policy Date: January 1, 2020
Original Policy Date: December 2012

Related Policies:
1.01.17 - Pelvic Floor Stimulation as a Treatment of Urinary Incontinence
2.01.58 - Transanal Radiofrequency Treatment of Fecal Incontinence
7.01.19 - Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
7.01.29 - Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Description

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction.

The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence.

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4-S3) via the posterior tibial nerve located near the ankle. The lumbosacral nerves control the bladder detrusor and perineal floor.

Administration of PTNS consists of inserting a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses as evidenced by a tickling sensation and plantar flexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

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PTNS is less invasive than traditional sacral nerve neuromodulation, which has been successfully used to treat urinary dysfunction but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

**OBJECTIVE**

The objective of this evidence review is to determine whether the use of percutaneous tibial nerve stimulation improves the net health outcome in individuals who have urinary dysfunction associated with overactive bladder syndrome, neurogenic bladder, or fecal incontinence.

**POLICY STATEMENT**

Percutaneous tibial nerve stimulation for an initial 12-week course is considered *medically necessary* for individuals with non-neurogenic urinary dysfunction including overactive bladder who have both:

- failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals; and
- failed pharmacologic therapy following 4 to 8 weeks of treatment without meeting treatment goals.

Maintenance therapy using monthly percutaneous tibial nerve stimulation is considered *medically necessary* for individuals following a 12-week initial course of percutaneous tibial nerve stimulation that resulted in improved urinary dysfunction meeting treatment goals.

Percutaneous tibial nerve stimulation is considered *investigational* for all other indications, including but not limited to the following:

- Neurogenic bladder dysfunction
- Fecal incontinence.

**POLICY GUIDELINES**

Patients may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals (Gormley et al [2015]).

Patients may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals (Gormley et al [2015]).

Annual evaluation by a physician may be performed to ensure efficacy is continuing for maintenance percutaneous tibial nerve stimulation treatments.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

In 2005, the Urgent PC Neuromodulation System was the initial PTNS device cleared for marketing by FDA through the 510(k) process to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. Additional percutaneous tibial nerve stimulators have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The Urgent PC Neuromodulation System and NURO™ Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.
Wireless technology is evolving for the treatment of overactive bladder; it is approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator activated by an external device worn at the ankle.

Table 1. FDA-Cleared Percutaneous Tibial Nerve Stimulators (FDA Product Code: NAM)

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Cleared</th>
<th>510 (k)</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent PC Neuromodulation System</td>
<td>Uroplasty, now Cogentix Medical</td>
<td>Oct 2005</td>
<td>K05 202 5</td>
<td>Treatment of urinary urgency, urinary frequency, and urge incontinence</td>
</tr>
<tr>
<td>Urgent PC Neuromodulation System</td>
<td>Uroplasty, now Cogentix Medical</td>
<td>Jul 2006</td>
<td>K06 133 3</td>
<td>FDA determined the 70% isopropyl alcohol prep pad contained in the kit is subject to regulation as a drug</td>
</tr>
<tr>
<td>Urgent PC Neuromodulation System</td>
<td>Uroplasty, now Cogentix Medical</td>
<td>Aug 2007</td>
<td>K07 182 2</td>
<td>Labeling update, intended use is unchanged</td>
</tr>
<tr>
<td>Urgent PC Neuromodulation System</td>
<td>Uroplasty, now Cogentix Medical</td>
<td>Oct 2010</td>
<td>K10 184 7</td>
<td>Intended use statement adds the diagnosis of overactive bladder</td>
</tr>
<tr>
<td>NURO™ Neuromodulation System</td>
<td>Advanced Uro-Solutions, now Medtronic</td>
<td>Nov 2013</td>
<td>K13 256 1</td>
<td>Treatment of patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

**RATIONALE**

**Summary of Evidence**

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and have failed behavioral and pharmacologic therapy who receive an initial course of percutaneous tibial nerve stimulation (PTNS), the evidence includes randomized sham-controlled trials, randomized controlled trials (RCTs) with an active comparator, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The SUMiT and the OrBIT trials are 2 key industry-sponsored RCTs. Systematic reviews that included these and other published trials have found short-term reductions in voiding dysfunction with PTNS. The largest, highest quality study was the double-blinded, sham-controlled SUMiT trial, which reported a statistically significant benefit of PTNS vs sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication therapy at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have overactive bladder syndrome that has failed behavioral and pharmacologic therapy who respond to an initial course of PTNS who receive maintenance PTNS, the evidence includes observational studies and systematic reviews. Relevant...
outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The SUmiT and the OrBIT trials each included extension studies that followed individuals who responded to the initial course of PTNS and continued to receive periodic maintenance therapy. There is variability in the interval between and frequency of maintenance treatments, and an optimal maintenance regimen remains unclear. There are up to 36 months of observational data available, reporting that there is a durable effect for some of these patients. While comparative data are not available after the initial 12-week treatment period, the observational data support a clinically meaningful benefit for use in individuals who have already failed behavioral and pharmacologic therapy and who respond to the initial course of PTNS. PTNS may allow such individuals to avoid more invasive interventions. Adverse events appear to be limited to local irritation for both short- and long-term PTNS use. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Typical regimens schedule maintenance treatments every 4-6 weeks. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have neurogenic bladder dysfunction who receive PTNS, the evidence includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but one performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors such as study populations and comparator interventions. Study findings have not reported that tibial nerve stimulation significantly reduced incontinence symptoms and improved other outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive PTNS, the evidence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve simulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Urological Association et al

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2019) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer percutaneous tibial nerve stimulation (PTNS) as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain.

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2015) practice bulletin on the treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.
American Gastroenterological Association

The American Gastroenterological Association (2017) issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence. The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI [fecal incontinence] in clinical practice."

Canadian Urological Association

The Canadian Urological Association (2019) published guidelines for the diagnosis, management, and surveillance of neurogenic bladder dysfunction. The guidelines stated that "PTNS appears to be well-tolerated and effective in small studies, with minimal reported adverse events, mainly mild to moderate pain at the puncture site." This statement carried a grade C rating, with remarks that the evidence was limited by few studies, heterogeneous populations, small sample sizes, and nonrandomized study designs. Although some efficacy has been demonstrated in patients with multiple sclerosis, the guidelines caution that it is unknown which subgroups of neurogenic bladder dysfunction will respond best to this therapy.

European Association of Urology

The European Association of Urology (2018) conducted a review of third-line therapies for patients with overactive bladder who do not respond to bladder training or pharmacotherapy. The Association found that botulinum toxin, PTNS, and sacral nerve stimulation may be effective treatments for OAB. There was no high-quality evidence showing the superiority of one therapy over another. Age, comorbidities, patient preference, and surgical expertise were factors to be considered when treatment decisions are made. Table 7 compares the treatment options.

Table 7. Comparisons of SNM, PTNS, and Botulinum Toxin as Treatments for Overactive bladder

<table>
<thead>
<tr>
<th></th>
<th>SNM</th>
<th>PTNS</th>
<th>Botulinum Toxin Type A</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA/EC approval</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Long-term results</td>
<td>Yes</td>
<td>No</td>
<td>Limited</td>
</tr>
<tr>
<td>Advantages</td>
<td>Minimally invasive</td>
<td>Noninvasive</td>
<td>Minimally invasive</td>
</tr>
<tr>
<td></td>
<td>Effective for urinary and bowel disorders</td>
<td>Uncomplicated procedure</td>
<td>Direct effect</td>
</tr>
<tr>
<td>Disadvantages</td>
<td>Permanent implant</td>
<td>May need to repeat procedure every 8-12 wk</td>
<td>Repeat after 6-12 mo</td>
</tr>
<tr>
<td></td>
<td>Battery replacement every 5-8 y</td>
<td>Inferior efficacy</td>
<td>Need for CISC</td>
</tr>
<tr>
<td>Reversibility</td>
<td>Removal of implant</td>
<td>Instantly reversible</td>
<td>After 6 mo</td>
</tr>
</tbody>
</table>

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Adverse events

- Wound infection
- Device-related pain
- Device malfunction
- None
- Urinary retention
- Urinary tract infection
- Hematuria


U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2012</td>
<td>New policy</td>
<td>Policy updated with literature review. References 5, 6, 8-10, 12-15, 17 and 20 added; other references renumbered or removed. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; reference 1 added, 5 updated; policy statement unchanged.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review; reference 1 added, 5 updated; policy statement unchanged.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; Title changed to “Percutaneous Tibial Nerve Stimulation.” “Posterior” changed to “percutaneous” in existing policy statement. Policy statement edited to not medically necessary for all indications with bullet points for urinary and fecal incontinence. Reference 17-19 added.</td>
</tr>
</tbody>
</table>

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<th>Date</th>
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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>June 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through November 30, 2015; references 15, 17, 19-25, 27-28, and 30-31 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through September 15, 2017; reference 18 added; reference 31 updated. Revised policy statements for use of PTNS in OAB syndrome that has failed behavioral and pharmacologic therapy. In these patients, PTNS is considered medically necessary as an initial course of therapy and maintenance therapy for individuals who respond to initial course. Percutaneous tibial nerve stimulation changed from not medically necessary to investigational (due to FDA 510k approval status) for all other indications, including but not limited to the following: Neurogenic bladder dysfunction; Fecal incontinence.</td>
</tr>
<tr>
<td>December 2018</td>
<td></td>
<td>Policy updated with literature review through June 4, 2018; references 13-14, 27, 32, 34, and 37 added. Policy statements are unchanged.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 31, 2019; references added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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